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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,949	04/13/2004	Rong-Kun Chang	063089-0129	3599

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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/822,949	CHANG, RONG-KUN	
	Examiner	Art Unit	
	BLESSING M. FUBARA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5,7 and 14-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-5, 7 and 14 -18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner acknowledges receipt of request for extension of time filed 11/25/08 and 1/29/09; request for continued examination filed under 37 CFR 1.114, amendment and remarks filed 1/29/09. Claim 2 and 8-13 are canceled. Claims 1, 4, 5 and 14 are amended. New claims 16-18 are added. Claims 1, 3-5, 7 and 14-18 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/29/09 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 3-5, 7 and 14-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejections.

5. Claim 1 requires a sustained release pharmaceutical to consists (i) and (ii). The consisting language excludes the presence of granulating fluid that is required in all the compositions. Thus, a composition that does not have at least a granulating fluid is not envisioned at the time the invention is filed.

6. Correction and/or explanation are respectfully requested.

7. Claims 3, 14 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claims 3 and 14 appear to violate the requirement of claim 1 that the sustained release matrix consists of (i) and (ii) because the comprising language of claim 14 opens up the matrix and the layered tablet of claim 3 appears to have matrix that comprises components other than (i) and (ii).

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-3, 5, 7 and 14-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Faour et al. (US 6,004,582).

Faour discloses a multi-layered delivery device (abstract), that is "useable in different environments for use of the osmotic device include biological environments such as the oral, ocular, nasal, vaginal, glands, gastrointestinal tract, rectum, cervical, intrauterine, arterial, venous, otic, sublingual, dermal, epidermal, subdermal, implant, buccal, bioadhesive, mucosal and other similar environments. Likewise, it may be used in aquariums, industrial warehouses, laboratory facilities, hospitals, chemical reactions and other facilities" (column 4, lines 34-42). The dosage form is in the form of a tablet, pill, sphere, bar, plate or granule (column 6, line 7). The core of the tablet can comprise a number of agents such as osmagents, buffering agents, antioxidants, acacia, alginic acid, polyvinylpyrrolidone, methylcellulose, polyethylene glycol and many more that used with active agents in tablet formulation (column 9, line 28, 38-65; column 10, lines 14-57) and these materials used in the core or matrix of tablets meet the polymer requirements of claim 2. The multi-layered nature of the dosage form meets claim 3. Claim 5 describes the properties of the dosage form. The limitation of new claim 16 is directed to the property of the composition and in the same way, the recitation that the pharmaceutically or nutritionally active agent "is not absorbed through the oral mucosa to a substantial extent" is a property of the composition with a note that substantial is relative. The process of preparation of the dosage form is exemplified in at least Examples 1-4 and method claim 14 reads on Faour's method. Faour formulates a number of active agents as multilayered tablets (column 13, line 38 to column 16, line 44) and included in this list is riboflavin (column 16, line 31) with the teaching of the riboflavin meeting claim 7. The polyvinylpyrrolidone, methylcellulose and polyethylene glycol meet the limitation of new claim 17. The retaining means is a mucoadhesive and at least the hydroxypropylmethyl cellulose of Faour (column 6, line 26) meets

the mucoadhesive of claims 4 and 15 and thus the retaining means of claims 1, 5. At least the ethyl cellulose (column 6, line 27) meets new claim 18.

Response to Arguments

11. Applicant's arguments filed 1/29/09 have been fully considered but they are not persuasive.

12. Applicant argues that the Faour teaches semipermeable membrane that is not in the claimed invention. The examiner disagrees because the semipermeable membrane is not in the matrix of Faour. lease pharmaceutical dosage form and the dosage form of Faour is a sustained release dosage form; b) holding the sustained delivery dosage form in a buccal or sublingual location is the intended route of administration and the dosage form of Faour is intended for oral or buccal administration and when administered orally or through the buccal cavity, the dosage form is resident in the buccal or oral cavity for a time such that when a release occurs in the buccal cavity as applicant asserts, the active agent released is inherently swallowed for absorption in the gastrointestinal tract because Faour is clear that the active agent(s) is released in the stomach and in the intestines (column 5, lines 39 and 45). c) Although applicant states that Faour teaches an osmotic device that delivers active agent "to benefit the environment of use" that includes sublingual and buccal environments where the active agents are absorbed into the local sublingual and buccal environments, applicant acknowledges that there are other dosage forms of Faour that have active agents that are intended to be active in different local environments further acknowledging Faour's teaching that the active agent is released in the stomach and the intestines (column 5, lines 39 and 45). d) Furthermore, it is noted that because Faour teaches the sustained release dosage form of the claims, it flows that the dosage forms of

Faour would be capable of being held in the oral/buccal cavity for release and absorption in the stomach and intestines (gastrointestinal tract).

13. Claims 1, 4, 5, 7 and 14-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Lerner et al. (US 6,197,331).

Lerner discloses controlled release solid composition for the oral cavity or pharmaceutical oral patch (abstract) with the disc of claims 14 and 15 reading on the patch; the composition contains adhesive and release layer (column 8, lines 20-25) meeting the requirement for as layered dosage form in which one surface is adhesive, thus meeting claim 4 and another surface, non-adhesive (column 7, lines 53 and 54); polymer in the adhesive layer is EUDRAGIT type polymer (column 11, lines 24 and 25; column 7, lines 25-28, 45-50); the matrix can also contain plasticizers such as polyethylene glycol, castor oil (column 11, line 66 to column 12, line 5) with the polymer or the oil meeting new claim 17. Lerner specifically teaches that "any agent can be used, depending on the purpose of therapy" (column 15, lines 12 and 13) and proceeds to name specific ones and cyclosporin is mentioned as a peptide or protein drug (column 16, lines 52-56) meeting claim 7. The mixing of the polymer with the active agent and eventually formulating the composition into patch (column 17, lines 26-34) meets the requirements of the method claims 14 and 15. The limitation of new claim 16 is directed to the property of the composition and in the same way, the recitation that the composition "is not absorbed through the oral mucosa to a substantial extent is a property of the composition so that Lerner meets the claim. Lerner thus teaches all the limitations of the designated claims. The adhesive material

which includes EUDRAGIT (column 11, lines 16-53) meets claim 4 and thus the retaining device of claims 1, 5 and 15. The non-adhesive component (claim 3) meets new claim 18.

Response to Arguments

14. Applicant's arguments filed 1/29/09 have been fully considered but they are not persuasive.

15. Applicant says that Lerner teaches the presence of plasticizer that is not included in the claimed composition. The examiner disagrees because the matrix composition of claim 1 "comprises --- location" and the comprising language does not exclude plasticizer of Lerner.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/
Examiner, Art Unit 1618